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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,105	03/07/2000	ZIVA MESSIKA	MESSIKA=2	9465

7590

02/11/2003

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/445,105

Applicant(s)

MESSIKA ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2002 and 14 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/02 has been entered. An action on the RCE follows.

2. Applicant has amended claims 1-3, 5-8 and 10-12. Claims 1-12 are pending.

3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph withdrawn

4. Applicants amendment has obviated the rejection of claim 7 over lack of written description and enablement.

Claim Rejections - 35 USC § 112, second paragraph withdrawn

5. Applicants amendment has obviated the rejection of claim 2 as vague and indefinite for reciting the term "capable".

6. Applicants amendment has also obviated the rejection of claim 7 as vague and indefinite for reciting the term "variant".

Claim Rejections - 35 USC § 102, maintained

7. The rejection of claims 1, 2, 4, 7 and 12 under 35 U.S.C. § 102(b) as anticipated by Korn et al (1988) is maintained for reasons stated in Paper Nos: 8 and 10.

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Applicant argues that the supernatant of Korn et al. is not isolated. However, as indicated in Korn et al. (page:354, 1st paragraph) the reference does teach an isolated metabolically labeled TNF for immunoprecipitation experiments. Absent evidence to the contrary the Office is assuming that an "isolated" protein is a "substantially homogeneous" . The specification on page: 7 in fact recites that the substantially homogeneous glycosylated TNF was isolated. Furthermore, Korn et al. teaches that the human TNF that was isolated indeed was TNF-alpha (abstract).

With respect to the arguments on glycosylation of the human TNF-alpha, the human TNF-alpha produced by CHO cells are glycosylated. Korn et al. teach the expression of human TNF-alpha in CHO cells. Glycosylation is an inherent property of the protein produced by CHO cells (mammalian cells). A compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43). Therefore, Korn et al anticipate the instant invention.

Claim Rejections - 35 USC § 102, withdrawn

8. The rejection of claims 1, 2, 4 and 7-12 under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (1991) is withdrawn because Applicant has amended the claims to recite only TNF-alpha.

Claim Rejections - 35 USC § 103, maintained

9. The rejection of claims 3, 5, 6 and 8-11 under 35 U.S.C. § 103(a) as being unpatentable over Korn (1988) in view of Allet (U.S. Patent No: 5,487,984) is maintained.

Applicant cites several references to suggest that the state of the art did not recognize that the human TNF alpha was glycosylated. They further assert that they were the first to "discover" that human TNF alpha was glycosylated. However, the expression of glycosylated human TNF alpha protein in CHO cells is an inherent function of human TNF alpha. Thus, the properties of this compound are inseparable even though, the art at that time did not recognize it. The observation by the Applicant that the protein of the prior contained a specific property is not the basis for patenting a known prior art compound. Furthermore, as indicated in the previous Office action (Paper No: 10) Allet reference was introduced by the Office to describe the purification of TNF (column 6, lines 61-67), compositions and treatment of human diseases (column 7, lines 35-43, and column 12, line 4, to column 13, line 5). Furthermore, using an eukaryotic host to produce the protein will avoid the antigenic effects often associated with bacterially grown proteins. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods disclosed in Korn et al. to produce and purify the glycosylated TNF protein, obtain compositions and use it in treating human disease as taught by Allet et al. One of ordinary skill would have been motivated with reasonable expectation of success to modify the methods of Korn et al. because Allet et al. teach that recombinant TNF can be purified and formulated into compositions for treatment of human diseases (column 6, lines 61-67; column 7, lines 35-43 and column 12, line 4 to column 13, line 5). Therefore, the instant invention is *prima facie* obvious over Korn et al. (1988) in view of Allet et al. (U.S. Patent No: 5,487,984) and the rejection is maintained

Claim Rejections - 35 USC § 103, withdrawn

10. The rejection of claims 3, 5, 6 and 8-11 under 35 U.S.C. 103(a) as being unpatentable over Nakagawa et al. (1991) in view of Allet et al. in (U.S. Patent No: 5,487,984) is withdrawn because Applicant has amended the claims to recite only TNF-alpha.

11. The following rejections are necessitated by the amendment to the claims.

Claim Rejections - 35 USC § 112, second paragraph

12. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12a. Claim 7 is rejected as being vague and indefinite in the recitation of the term "mutant thereof encodes human TNF-alpha ". It is unclear how the DNA encoding the TNF-alpha also encode the mutant TNF-alpha.

13. No Claims are allowable over prior art.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

JS
February 10, 2003